DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Haider Biologics, LLC
Gustavo R. Prado, PhD
Vice President of R&D
9930 Mesa Rim Road
San Diego, California 92121

February 23, 2015

Re: K141429
Trade/Device Name: Sorrento™ Bone Graft Substitute
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: January 22, 2015
Received: January 26, 2015

Dear Dr. Prado:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141429

Device Name
Sorrento™ Bone Graft Substitute

Indications for Use *(Describe)*
Sorrento Bone Graft Substitute is intended for use as a bone void filler to fill voids or gaps of the skeletal system in the extremities and pelvis not intrinsic to the stability of the bony structure. Sorrento Bone Graft Substitute is also indicated for use in the treatment of surgically treated osseous defects or osseous defects created from traumatic injury to the bone. Sorrento Bone Graft Substitute must be wetted with bone marrow aspirate. Following placement in the bony void or gap (defect), Sorrento Bone Graft Substitute is resorbed and replaced with bone during the healing process.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Submitter:

Haider Biologics, LLC
9930 Mesa Rim Drive, San Diego, CA 92121

Phone: (858) 202-1540
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Contact: Gustavo R. Prado, PhD
Title: Vice President of R&D
E-mail: gprado@haiderbiologics.com

Date Prepared:

February 18, 2015

Subject Device:

Trade Name: Sorrento™ Bone Graft Substitute
Common Name: Bone Void Filler

Classification Name: Resorbable Calcium Salt Bone Void Filler Device
Regulation: 21 CFR 888.3045

Device Class: Class II
Product Code: MQV
Review Panel: Orthopedic

Predicate Devices:

510(k) #	*Trade Name*	*Product Code*
K032288	Vitoss® Scaffold Foam Bone Graft Material (Orthovita, Inc.)	MQV

Device Description:

Sorrento Bone Graft Substitute is a resorbable bone void filler made from a matrix of highly purified collagen (ASTM F2212) that has high porosity beta tricalcium phosphate (TCP) granules (ASTM F1088) dispersed throughout. The implant is provided as sterile, non-pyrogenic, and for single use in double peel packages.

Indications for Use:

Sorrento Bone Graft Substitute is intended for use as a bone void filler to fill voids or gaps of the skeletal system in the extremities and pelvis not intrinsic to the stability of the bony structure. Sorrento Bone Graft Substitute is also indicated for use in the treatment of surgically treated osseous defects or osseous defects created from traumatic injury to the bone. Sorrento Bone Graft Substitute must be wetted with bone marrow aspirate. Following placement in the bony void or gap (defect), Sorrento Bone Graft Substitute is resorbed and replaced with bone during the healing process.

Technological Characteristics:

The subject device is substantially equivalent to the cited legally marketed predicate device. The subject device has the same technological characteristics including design, materials, operating principle and indications for use.

Chart comparing subject device to the predicate device:

Characteristic	Substantially Equivalent?	Impact on Safety & Performance
Design	YES	None
Material Characterization	YES	None
Biocompatibility	YES	None
Sterilization	YES	None
Components of Device (Material)	YES	None
Dimensional Specifications	YES	None
Physical Form (Sponge)	YES	None

Non-Clinical Testing:

Distal femoral defect model in rabbits was used to compare the subject device to the predicate device at 6 and 12 weeks following implantation. Performance was evaluated radiographically and histomorphometrically. Study data demonstrated that the subject device is substantially equivalent with the predicate device.

In addition, substantial equivalence of the Sorrento Bone Graft Substitute was supported by evaluation per ASTM F1088 (for beta tricalcium phosphate) and ASTM F2212 (for collagen).

Clinical Testing:

Clinical performance data were not required to determine substantial equivalence

Conclusions:

Conclusions drawn from the non-clinical tests demonstrated that the subject device possessed at least equivalent performance characteristics as the predicate device, and that overall the subject device is substantially equivalent.